DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

13134

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

CERTIFIED MAIL-RETURN RECEIPT REQUESTED

WARNING LETTER

May 30, 2001

Tuan H. Pham, President
Phamatech, Inc.
9530 Padgett Street
Suite 101
San Diego, CA 92126

WL-49-01

Dear Mr. Pham:

During an inspection of your firm located in San Diego, California, on May 1 to May 4, 2001, our investigator determined that your firm manufactures in vitro diagnostic tests. In vitro diagnostic test products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act.

Our inspection disclosed that these devices are adulterated within the meaning of Section 510(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, and storage are not in conformance with the Good Manufacturing Practice (GMP) requirements for the Quality System Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to establish procedures for conducting management reviews [21 CFR 820.20(c)]. Specificially, no written procedures have been established to ensure that management with executive responsibility shall review the suitability and effectiveness of the quality system at defined intervals.

2. Failure to establish complete procedures for conducting quality audits [21 CFR 820.22]. Specificially, your written procedures do not specify that systematic independent examinations of your complaint handling and purchasing activities are conducted at defined intervals and at sufficient frequency to determine whether both quality system activities comply with your quality system requirements.

3. Failure to establish complete procedures to identify training needs of all employees engaged in your quality system activities [21 CFR 820.25(b)]. Specificially, there was no documentation describing the training and training needs for employees conducting your quality audit activities.

4. Failure to control procedures for addressing the evaluation and disposition of non-conforming product [21 CFR 820.90(a)]. Specificially, reports for the disposition of non-conforming products were not completely documented to include the individuals with authority for determining the disposition of non-conforming product, the prevention measures taken to prevent recurrences of similar problems, and any necessary evaluation(s) needed by management to ensure that all elements of the quality system requirements are met.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the Form FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance system. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal Agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no pre-market submissions for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates For Exportability will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

If you have any questions relating to this letter please contact Senior Compliance Officer, Dannie E. Rowland at (949) 798-7649.

Please submit your response to:

Thomas L. Sawyer
Director, Compliance Branch
Food and Drug Administration
19900 MacArthur Boulevard, Suite 300
Irvine, CA 92612-2445

Sincerely,

Alonza E. Cruse
District Director
Los Angeles District Office

Cc: State Department of Public Health
Envirnomental Health Services
Attn: Chief, Food and Drug Branch
601 North 7th Street, MS-35
Sacramento, CA 94234-7320